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JAN 17 2006

Thomas D. Hoffman  
Schering Corporation, Patent Department  
K-6-1 1990  
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Kenilworth NJ 07033-0530

In Re: Patent Term Extension  
Application for  
U.S. Patent No. Re. 37,721

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. Re. 37,721, which claims the human drug product ZETIA® (ezetimibe), and a method of its use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 497 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 497 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 17, 2003 (68 Fed. Reg. 18992) would be 948 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,680 - 390) + 303 \\ &= 948 \text{ days (2.6 years)}\end{aligned}$$

Since the regulatory review period began May 23, 1997, before the patent issued (June 16, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 23, 1997 to, and including, June 16, 1998 is 390 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 948 days, would extend the patent from June 16, 2015 to January 19, 2018, which is beyond the 14-year limit (the approval date is October 25, 2002, thus the 14-year limit is October 25, 2016). The period of extension is thus limited to 497 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 16, 2015, to and including October 25, 2016, or 497 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: Re. 37,721  
Granted: May 28, 2002<sup>1</sup>  
Original Expiration Date<sup>2</sup>: June 16, 2015  
Applicant: Stuart B. Rosenblum, et al.  
Owner of Record: Schering Corporation  
Title: HYDROXY-SUBSTITUTED AZETIDINONE COMPOUNDS USEFUL AS HYPOCHOLESTEROLEMIC AGENTS  
Product Trade Name: ZETIA® (ezetimibe)  
Term Extended: 497 days  
Expiration Date of Extension: October 25, 2016

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Kery A. Fries  
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Office of Patent Legal Administration  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Office of Regulatory Policy  
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5600 Fishers Lane  
Rockville, MD 20857

RE: ZETIA® (ezetimibe)  
FDA Docket No.: 03E-0035

Attention: Claudia Grillo

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<sup>1</sup>The reissue grant date is May 28, 2002, however, the grant date of U.S. Patent No. 5,767,115, the patent upon which Reissue Patent No. 37,721 is based, was June 16, 1998.

<sup>2</sup>Subject to the provisions of 35 U.S.C. § 41(b).